

FORM 14

SMALL BUSINESS IMPACT STATEMENT FORM

See SDCL 1-26-2.1

(NOTE: This form must be signed by either the head of the agency or the presiding officer of the board or commission empowered to adopt the rules. Check your statutes to see who is authorized to promulgate rules. A small business is defined as any business with 25 or fewer full-time employees. When a set of rules is proposed, a general summary shall be provided; each proposed rule amendment shall also be explained thoroughly. In the case of a large set of proposed rules which all have a single purpose and impact, one explanation is sufficient. The law makes it clear that agencies or commissions shall use readily available information and existing resources to prepare the impact statement.)

1. Our agency has determined that the rule/s we are proposing have the following type of impact on small businesses:
- ☒ Direct impact *(please complete remainder of form)*
 - ☐ Indirect impact *(please provide a brief explanation, then sign, date, and submit form. Questions 2 through 8 do not need to be answered)*
 - ☐ No impact *(please provide a brief explanation, sign, date, and submit form - Questions 2 through 8 do not need to be answered)*

2. A general narrative and overview of the effect of the rule(s) on small business - written in plain, easy to read language:

This proposed rule states the requirements for the use of mifepristone and misoprostol as a medical abortion to end a pregnancy be prescribed and dispensed only by a licensed physician in a licensed abortion facility consistent with SDCL 34-23A. The abortion facility shall also collect and maintain certain information and report the same.

3. What is the basis for the enactment of the rule(s)?
- ☐ Required to meet changes in federal law
 - ☐ Required to meet changes in state law
 - ☐ Required solely due to changes in date (i.e. must be changed annually)
- Other: Change is required per the Governor's Executive Order 2021-12
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4. Why is the rule(s) needed?
- To protect the health and safety of women that is at-risk due to the expected FDA lifting of additional safety protocols regarding the use of mifepristone and misoprostol. The rule requires that mifepristone and misoprostol used for a medical abortion may only be prescribed and dispensed by a licensed physician and administered in person in a licensed abortion facility consistent with SDCL 34-23A, and to require reporting of certain information.

5. What small businesses or types of small businesses would be subject to the rule?
- Licensed abortion facilities

6. Estimate the number of small businesses that would be subject to the rule.
☐ X 1-99 ☐ 100-499 ☐ 500-999 ☐ 1,000-4,999 ☐ More than 5,000
☐ Unknown - please explain _____
7. Are small businesses required to file or maintain any reports or records under this rule?
☒ Yes ☐ No
- a. If "yes," how many reports must a small business submit to the state on an annual basis? None. The Department conducts inspections or audits.
- b. If "yes," how much ongoing recordkeeping within the business is necessary? Minimal. Abortion facilities already retain much of the information that is required to be reported/tracked.
- c. If "yes," what type of professional skills would be necessary to prepare the reports or records?
☐ The average owner of a small business should be able to complete the reports and/or records with no assistance
☐ It is likely that a bookkeeper for a small business should be able to complete the reports and/or records
☐ It is likely that a small business person would need the assistance of a CPA to complete the reports and/or records
☐ It is likely that a small business person would need the assistance of an attorney to complete the reports and/or records
☒ X Other Same staff that are currently reporting patient medical information.
☐ Unknown - please explain _____
8. Are there any less intrusive or less costly methods to achieve the purpose of the rule (i.e. fewer reports, less recordkeeping, lower penalties)?
☐ X No - please explain record keeping requirements are minimal
☐ Yes - please explain _____

11/8/2001
Dated

Kim Malsam-Rydon
Authorized Signature

Department of Health
Name of Agency